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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,696,949

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,696,949, which claims the human drug product FARESTON® (toremifene citrate) and the method of use of toremifene citrate, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension for a period of five years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 11, 1998 (63 Fed. Reg. 42857). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (2,828 - 174) + 878 \\ &= 2,205 \text{ days (6.04 years)}\end{aligned}$$

Since the regulatory review period began April 8, 1987, before the patent issued (September 29, 1987), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From April 8, 1987 to September 29, 1987 is 174 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A) and the 14 year limitation of 35 U.S.C. § 156(c)(3) does not further reduce the period of extension determined above, the period of extension will be for five years.

Upon issuance of the certificate of extension, the following information will be published in the

Official Gazette:

U.S. Patent No.:	4,696,949
Granted:	September 29, 1987
Original Expiration Date:	September 29, 2004
Applicant:	Reijo J. Toivola, et al.
Owner of Record:	Orion-Yhtymä Oy
Title:	Novel Tri-Phenyl Alkane and Alkene Derivatives and Their Preparation and Use
Classification:	514/648
Product Trade Name:	FARESTON® (toremifene citrate)
Term Extended:	Five years
Expiration Date of Extension :	September 29, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

  
Karin L. Tyson

Senior Legal Advisor/Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: David T. Read  
Acting Director Regulatory Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

RE: FARESTON®  
FDA Docket No.: 97E-0357